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09/738,212

CASE TX/4-118-8353B



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| FILING BY "EXPRESS MAIL" UNDER 37 CFR 1.10 |                  |
| EV336718560 US                             | December 2, 2005 |
| Express Mail Label Number                  | Date of Deposit  |

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE PATENT OF

NEUER ET AL.

U.S. PATENT NO: 6,951,841B2

ISSUED: OCTOBER 4, 2005

FOR: PHARMACEUTICAL COMPOSITIONS OF MACROLIDES OR  
CYCLOSPORINE WITH A POLYETHOXYLATED SATURATED HYDROXY-  
FATTY ACID

Mail Stop Petition  
Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

REQUEST FOR RECONSIDERATION OF FINAL PATENT TERM ADJUSTMENT DETERMINATION  
UNDER 37 CFR §1.705(d)

Sir:

The final patent term adjustment for U.S. Patent No. 6,951,841B2 issued on October 4, 2005 was determined by the PTO to be 527 days which according to the PAIR system was calculated based on the total number of days due to PTO delay, 659 days, less the total number of days due to Patentees' delay, 132 days. Copies of the cover page of U.S. Patent No. 6,951,841B2 and the patent term adjustment history printout from the PAIR system are attached hereto. In making this determination, it appears that the PTO in calculating the total number of days due to PTO delay considered the Board of Patent Appeals and Interferences (BPAI) decision favorable (reversed) when in fact the BPAI decision was unfavorable. A detailed review of the file history of this patent revealed that the patent term adjustment of 527 days was incorrect and that the correct patent term adjustment should be 76 days. Patentees respectfully request that the patent term adjustment be revised to 76 days. The bases for this correction is indicated below.

37 CFR §1.702(b) indicates that the term of a patent shall be adjusted if the issuance of the patent was delayed due to the failure of the Office to issue a patent within three years after the application was filed under 35 U.S.C. §111(a), but not including any time consumed by review by the BPAI. In the present case, the three year period as measured from the application filing date of December 15, 2000 ended on December 15, 2003, however, any days that were consumed by review by the BPAI before December 15, 2003 cannot be included in measuring the three year period and must be added onto the projected issue date of December 15, 2003. The total number of days consumed by the BPAI as determined from the Notice of Appeal dated August 16, 2002 to the BPAI decision dated November 10,

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2004 is 451 days. Accordingly, the addition of 451 days from December 15, 2003 results in an adjusted patent issue date of March 10, 2005.

The patent actually issued on October 4, 2005. Thus, the total number of days of patent term adjustment due to PTO delay as measured from the adjusted issue date of March 10, 2005 to the actual issue date of October 4, 2005 is 208 days.

With respect to 37 CFR §1.704(b), the PAIR system correctly indicated a reduction of patent term adjustment of 132 days due to Patentees' delay as measured from the three-month period from the date of the Office Action of July 18, 2001 to the Patentees' Response received February 27, 2002. Accordingly, Patentees are entitled to receive a final patent term adjustment of 76 days as determined from 208 days due to PTO delay less 132 days due to Patentees' delay.

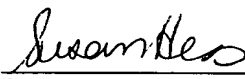
It is further noted that U.S. Patent No. 6,951,841B2 is subject to a terminal disclaimer over copending Application Ser. No. 09/547,802 (the '802 application). The PAIR system indicated that as of November 9, 2005 the '802 application is on appeal awaiting decision of the BPAI.

In view of the foregoing, it is respectfully requested that this Request for Reconsideration be favorably considered and that the PTO send out a Certificate of Correction wherein the cover page of the subject U.S. patent reflects a final patent term adjustment of 76 days.

Please charge the \$200 fee required by 37 CFR §1.18(e) and any other fees that may be required to Deposit Account No. 19-0134 in the name of Novartis Corporation. An additional copy of this Request for Reconsideration of Final Patent Term Adjustment is enclosed.

Respectfully submitted,

Novartis  
Corporate Intellectual Property  
One Health Plaza, Building 104  
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\_\_\_\_\_  
Susan Hess  
Attorney for Applicants  
Reg. No. 37,350

Attachs.: cover page of U.S. Patent No. 6,951,841B2

Copy of PAIR printout

Extra copy of Request of Reconsideration of Final Patent Term Adjustment  
postcard

Date: December 2, 2005

Printer Friendly  
09/738,212PHARMACEUTICAL COMPOSITIONS OF MACROLIDES OR CYCLOSPORINE WITH A  
POLYETHOXYLATED SATURATED HYDROXY-FATTY ACID

## Patent Term Adjustment History

| Patent Term Adjustment (PTA) for Application Number: 09/738,212 |            |                             |      |
|---|------------|-----------------------------|------|
|   |            |                             | Days |
| Filing or 371(c) Date:  | 12-15-2000 | USPTO Delay (PTO):          | 659  |
| Issue Date of Patent:   | 10-04-2005 | Three Years:                | -    |
| Pre-Issue Petitions (days):                                     | +0         | Applicant Delay(APPL):      | 132  |
| Post-Issue Petitions (days):                                    | +0         | Total PTA:                  | 527  |
| USPTO Adjustment(days):   | +0         | Explanation Of Calculations |      |

## Patent Term Adjustment History

| Date       | Contents Description                            | PTO(Days) | APPL (Days) |
|------------|---|-----------|-------------|
| 10-04-2005 | Patent Issue Date Used in PTA Calculation       |           |             |
| 09-14-2005 | PTA 36 Months                                   | 127       |             |
| 08-31-2005 | Receipt into Pubs                               | ↑         |             |
| 08-30-2005 | Dispatch to FDC                                 | ↑         |             |
| 08-30-2005 | Application Is Considered Ready for Issue       | ↑         |             |
| 08-25-2005 | Receipt into Pubs                               | ↑         |             |
| 07-07-2005 | Issue Fee Payment Verified                      | ↑         |             |
| 07-07-2005 | Issue Fee Payment Received                      | ↑         |             |
| 06-14-2005 | Workflow - File Sent to Contractor              | ↑         |             |
| 04-07-2005 | Mail Notice of Allowance                        | 393       |             |
| 04-04-2005 | Notice of Allowance Data Verification Completed | ↑         |             |
| 04-04-2005 | Case Docketed to Examiner in GAU                | ↑         |             |
| 04-04-2005 | Correspondence Address Change                   | ↑         |             |
| 01-12-2005 | Case Docketed to Examiner in GAU                | ↑         |             |
| 11-30-2004 | Paralegal TD Accepted                           | ↑         |             |
| 10-06-2004 | Mail Notice of Rescinded Abandonment            | ↑         |             |
| 10-06-2004 | Notice of Rescinded Abandonment in TCs          | ↑         |             |
| 10-06-2004 | Case Docketed to Examiner in GAU                | ↑         |             |
| 10-04-2004 | Petition to Revive Application - Granted        | ↑         |             |
| 07-15-2004 | Petition Entered                                | ↑         |             |
| 07-15-2004 | Workflow incoming petition IFW                  | ↑         |             |
| 05-03-2004 | Workflow incoming amendment IFW                 | ↑         |             |
| 03-15-2004 | Mailing of Abandonment after Board of Appeals   | ↑         |             |
| 03-11-2004 | Abandonment after Board of Appeals              | ↑         |             |
| 01-08-2004 | Amendment/Argument after BPAI Decision          | ↑         |             |
| 11-10-2003 | Mail BPAI Decision on Appeal - Affirmed         | 139       |             |
| 11-10-2003 | BPAI Decision - Examiner Affirmed               | ↑         |             |
| 05-22-2003 | Docketing Notice Mailed to Appellant            | ↑         |             |
| 05-20-2003 | Assignment of Appeal Number                     | ↑         |             |
| 05-02-2003 | Appeal Awaiting BPAI Docketing                  | ↑         |             |
| 03-26-2003 | Mail Reply Brief Noted by Examiner              | ↑         |             |
| 03-24-2003 | Reply Brief Noted by Examiner                   | ↑         |             |

|            |  |   |     |
|------------|--|---|-----|
| 03-06-2003 | Date Forwarded to Examiner                   | ↑ |     |
| 03-06-2003 | Case Docketed to Examiner in GAU             | ↑ |     |
| 02-24-2003 | Reply Brief Filed                            | ↑ |     |
| 01-15-2003 | Mail Examiner's Answer                       | ↑ |     |
| 01-13-2003 | Examiner's Answer to Appeal Brief            | ↑ |     |
| 11-06-2002 | Date Forwarded to Examiner                   | ↑ |     |
| 10-16-2002 | Appeal Brief Filed                           | ↑ |     |
| 08-16-2002 | Notice of Appeal Filed                       | ↑ |     |
| 08-16-2002 | Request for Extension of Time - Granted      | ↑ |     |
| 05-21-2002 | Mail Final Rejection (PTOL - 326)            | ↑ |     |
| 05-20-2002 | Final Rejection                              | ↑ |     |
| 03-15-2002 | Date Forwarded to Examiner                   | ↑ |     |
| 02-27-2002 | Response after Non-Final Action              | ↑ | 132 |
| 02-27-2002 | Request for Extension of Time - Granted      | ↑ | ↑   |
| 01-31-2002 | Case Docketed to Examiner in GAU             | ↑ | ↑   |
| 01-31-2002 | Case Docketed to Examiner in GAU             | ↑ | ↑   |
| 07-18-2001 | Mail Non-Final Rejection                     | ↑ | ↑   |
| 07-16-2001 | Non-Final Rejection                          | ↑ |     |
| 06-09-2001 | Date Forwarded to Examiner                   | ↑ |     |
| 06-06-2001 | Response to Election / Restriction Filed     | ↑ |     |
| 06-06-2001 | Request for Extension of Time - Granted      | ↑ |     |
| 05-07-2001 | Information Disclosure Statement (IDS) Filed | ↑ |     |
| 04-20-2001 | Mail Restriction Requirement                 | ↑ |     |
| 04-19-2001 | Requirement for Restriction / Election       | ↑ |     |
| 04-13-2001 | Information Disclosure Statement (IDS) Filed | ↑ |     |
| 04-09-2001 | Information Disclosure Statement (IDS) Filed | ↑ |     |
| 04-03-2001 | Case Docketed to Examiner in GAU             | ↑ |     |
| 02-27-2001 | Application Dispatched from OIPE             | ↑ |     |
| 02-23-2001 | Correspondence Address Change                | ↑ |     |
| 02-23-2001 | Correspondence Address Change                | ↑ |     |
| 01-30-2001 | IFW Scan & PACR Auto Security Review         | ↑ |     |
| 12-15-2000 | Preliminary Amendment                        | ↑ |     |
| 12-15-2000 | Initial Exam Team nn                         | ↑ |     |

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